#### **REMARKS**

# Summary of the Amendment

Claims 1-44 are pending with claims 1, 43 and 44 being in independent form.

# Summary of the Official Action

In the instant Office Action, the Examiner withdrew claims 4-7 as being directed to a non-elected species. Additionally, the Examiner rejected claims 1-3 and 8-42 as indefinite. Finally, the Examiner rejected claims 1-44 over the art of record. By the present amendment and remarks, Applicant submits that the rejections have been overcome, and respectfully requests reconsideration of the outstanding Office Action and allowance of the present application.

# Claims 4-7 Are Withdrawn by the Examiner

Claims 4-7 were withdrawn by the Examiner because, the Examiner asserts, these claims are readable on Figs. 41-42 instead of Figs. 36-40.

While Applicant disagrees that these claims cannot be read on the elected species, Applicant requests that these claims be rejoined if and when claim 1 is found to be allowed/allowable.

## Traversal of Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-3 and 8-42 were rejected under 35 U.S.C. § 112, second paragraph, as

being indefinite. Applicant respectfully disagrees and traverses this rejection.

The Examiner asserts that the claims are confusing and inaccurate because claim 1 recites that the second stop surface FSS extends inwardly from the body when in fact that this stop surface is shown in the drawings and described in the specification as being part of the body.

Applicant disagrees that the noted claim feature is confusing. There is no contradiction between the second stop surface FSS extending inwardly from the body (which is in fact shown in the drawings) and this stop surface being either integrally formed with the body (as is shown in e.g., Figs. 3 and 36) or formed on a separate part (see e.g., Fig. 17). In each of the disclosed embodiments, the second stop surface does in fact extend inwardly from the body and the Examiner has not demonstrated otherwise.

Applicant respectfully reminds the Examiner that Applicant is not required to limit the invention to only the preferred embodiments disclosed in the specification.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims under 35 U.S.C. § 112, second paragraph.

# Traversal of Rejection Under 35 U.S.C. § 102(b)/103(a)

Applicant respectfully traverses the rejection of claims 1-3, 8-23, 27-31 and 36-42 under 35 U.S.C. § 102(b) as anticipated or as unpatentable under 35 U.S.C. § 103(a) over US patent 6,156,051 to SCHRAGA.

The Examiner asserts that SCHRAGA discloses or suggests, among other things, a second stop surface that is non-movably coupled to the body and that at least partial

rotation of the front cover causes the skin engaging end to move axially relative to the second stop surface. Applicant respectfully disagrees.

While the Examiner has identified the second stop surface in SCHRAGA as the lower surface of member 174 in Fig. 16, the Examiner has apparently failed to appreciate that member 174 is part of member 20C which is threadably and movably connected to the body 20A via threads 170/172 (see col. 14, lines 17-35). Thus, the Examiner is not correct that member 174 is non-movably coupled to the body.

Furthermore, while the Examiner has asserted that partial rotation of cover 50 causes the skin engaging end to move axially relative to the second stop surface, and identified col. 14, lines 21-24 of SCHRAGA as disclosing this feature, the Examiner has failed to appreciate that because the cover 50 has a triangular cross-section and slides onto a triangular portion of the body 20, it cannot possibly rotate relative to the body 20. Furthermore, as col. 14, lines 21-24 of SCHRAGA merely discusses the adjustability of the upper housing 20A relative to the middle housing 20C, the Examiner cannot reasonably argue that either of these parts is a front cover. Applicant respectfully reminds the Examiner that the front cover recited in claim 1 is defined as having a skin engaging end that includes a lancet opening through which a lancet needle may extend. Neither of the body portions 20A and 20C include this feature.

Thus, Applicant submits that the above-noted document fail to disclose or suggest the features recited in at least independent claim 1. Because no proper modification of the above-noted document discloses or suggests at least the above-noted features of the instant invention, Applicant submits that no proper modification of this document can

render unpatentable the combination of features recited in at least independent claim 1.

Furthermore, Applicant submits that there is no motivation or rationale disclosed or suggested in the art to modify any of the applied document in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify this document, in the manner suggested by the Examiner. Therefore, Applicant submits that the invention as recited in at least independent claim 1 is not rendered obvious by any reasonable inspection of these documents.

Additionally, Applicant submits that dependent claims 2, 3, 8-23, 27-31 and 36-42 are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention. In particular, Applicant submits that no proper modification of SCHRAGA discloses or suggests, in combination: that the lancet device further comprises a back cap configured to move between a retracted position and an original position as recited in claim 2; that the back cap is configured to move the holding member to a retracted position as recited in claim 3; that the lancet device further comprises another spring for biasing the back cap towards an original position as recited in claim 8; that the main spring biases the holding member towards an extended position, and further comprising another spring for biasing the holding member in an opposite direction as recited in claim 9; that the main spring and said other spring are arranged to surround portions of the holding member as recited in claim 10; that the main spring is coupled one side of the holding member and to a surface of the body as recited in claim 11; that the holding member comprises cylindrical surfaces and a polygonal cross-sectional shape as recited in claim 12; that the lancet

device further comprises a locking member mounted to the rear end of the holding member as recited in claim 13; that the main spring surrounds a portion of the holding member and wherein the other spring is disposed between a surface of a back cap and the locking member as recited in claim 14; that the trigger is movably mounted to the body as recited in claim 15; that the front cover is removably mounted to the body as recited in claim 16; that the lancet device further comprises a mechanism for at least temporarily maintaining a depth setting position of the front cover as recited in claim 17; that the holding member comprises an integrally formed deflecting member that engages a surface of the body as recited in claim 18; that the front end comprises an opening that is configured to removably receive the lancet as recited in claim 19; that the lancet device further comprises a deflecting member configured to be deflected by the trigger as recited in claim 20; that the deflecting member is coupled to the holding member as recited in claim 21; that the deflecting member comprises an engaging surface that contacts a surface of the body as recited in claim 22; that the deflecting member is integrally formed with the holding member as recited in claim 23; that the holding member comprises a front portion that includes the front end and a rear portion that includes the rear end, wherein the front and rear portions are connected together as recited in claim 27; that the rear portion comprises a locking end which receives a locking member as recited in claim 28; that the front portion comprises a deflecting member configured to be deflected by the trigger as recited in claim 29; that the front cover rotates about an axis that runs through the lancet opening and the holding member as recited in claim 30; that the main spring is disposed between the trigger and a back cap as recited in claim 31; that the body comprises an ergonomic shape as recited in

claim 36; that the body comprises cylindrical surfaces as recited in claim 37; that the body comprises a plastic material as recited in claim 38; that the front cover comprises gripping protrusions as recited in claim 39; that the lancet device further comprises threads connecting the front cover to the body as recited in claim 40; a method of puncturing a surface of skin using the lancet device of claim 1, wherein the method comprises adjusting a set depth of penetration of the needle by rotating the front cover to a desired set position, disposing the skin engaging end of the lancet device against a user's skin, and triggering the trigger to cause the lancet needle to penetrate the user's skin, wherein the puncture allows a blood sample to be taken as recited in claim 41; and a method of using the lancet device of claim 1, wherein the method comprises rotating the front cover to a desired set position, moving the holding member to a retracted position, maintaining the holding member in the retracted position until the trigger is triggered, disposing the skin engaging end of the lancet device against a user's skin, and triggering the trigger to cause movement of the holding member as recited in claim 42.

Applicant requests that the Examiner reconsider and withdraw the rejection of the above-noted claims under 35 U.S.C. § 102(b)/103(a).

# Traversal of Rejections Under 35 U.S.C. § 103(a)

#### Over Schraga

Applicant respectfully traverses the rejection of claims 24-26 and 32-35 under 35 U.S.C. § 103(a) as unpatentable over SCHRAGA alone.

The Examiner acknowledges that SCHRAGA lacks, among other things, the

features recited in the above-noted claims such as the recited indicia and the recited twopiece body. However, the Examiner asserted that such features are taught in SCHRAGA and that it would have been obvious to one of ordinary skill in the art to combine the teachings of these documents. Applicant respectfully traverses this rejection.

Notwithstanding the Examiner's assertions as to what SCHRAGA discloses or suggests, Applicant submits that no proper combination of these documents discloses or suggests: inter alia, a second stop surface that is non-movably coupled to the body and that at least partial rotation of the front cover causes the skin engaging end to move axially relative to the second stop surface as recited in at least claim 1.

As explained above, while the Examiner has identified the second stop surface in SCHRAGA as the lower surface of member 174 in Fig. 16, the Examiner has failed to appreciate that member 174 is part of member 20C which is threadably and movably connected to the body 20A via threads 170/172 (see col. 14, lines 17-35). Thus, the Examiner is not correct that member 174 is non-movably coupled to the body.

Furthermore, while the Examiner has asserted that partial rotation of cover 50 causes the skin engaging end to move axially relative to the second stop surface, and identified col. 14, lines 21-24 of SCHRAGA as disclosing this feature, the Examiner has failed to appreciate that because the cover 50 has a triangular cross-section and slides onto a triangular portion of the body 20, it cannot possibly rotate relative to the body 20. Furthermore, as col. 14, lines 21-24 of SCHRAGA merely discusses the adjustability of the upper housing 20A relative to the middle housing 20C, the Examiner cannot reasonably argue that either of these parts is a front cover. Applicant respectfully reminds the

Examiner that the front cover recited in claim 1 is defined as having a skin engaging end that includes a lancet opening through which a lancet needle may extend. Neither of the body portions 20A and 20C include this feature.

Thus, Applicant submits that the above-noted document fails to disclose or suggest the features recited in at least independent claim 1. Because no proper modification of the above-noted documents discloses or suggests at least the above-noted features of the instant invention, Applicant submits that no proper modification of this document can render unpatentable the combination of features recited in at least independent claim 1.

Furthermore, Applicant submits that there is no motivation or rationale disclosed or suggested in the art to modify any of the applied document in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify this document, in the manner suggested by the Examiner. Therefore, Applicant submits that the invention as recited in at least independent claim 1 is not rendered obvious by any reasonable inspection of these documents.

Additionally, Applicant submits that dependent claims 24-26 and 32-35 are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention. In particular, Applicant submits that no proper modification of SCHRAGA discloses or suggests, in combination: that the lancet device further comprises indicia arranged on at least one of the front cover and the body as recited in claim 24; that the indicia is arranged on an outer circumferential surface of the body as recited in claim 25; that the indicia is arranged on an outer circumferential surface of the front cover as recited in claim 26; that

the body comprises a two-piece body as recited in claim 32; that the lancet device further comprises another spring axially retained between walls of the two-piece body as recited in claim 33; that the front cover is removably mounted to the two-piece body as recited in claim 34; and that the lancet device further comprises a back cap movably mounted to the two-piece body as recited in claim 35.

Applicant requests that the Examiner reconsider and withdraw the rejection of the above-noted claims under 35 U.S.C. § 103(a).

#### Over Slama with Schraga

Applicant respectfully traverses the rejection of claims 43 and 44 under 35 U.S.C. § 103(a) as unpatentable over US patent 4,469,110 to SLAMA in view of US patent 6,156,051 to SCHRAGA.

The Examiner acknowledged that SLAMA lacks, among other things, the features recited in the above-noted claims such as the recited main spring disposed between the front and rear ends of the holding member. However, the Examiner asserted that this feature is taught in SCHRAGA and that it would have been obvious to one of ordinary skill in the art to combine the teachings of these documents. Applicant respectfully traverses this rejection.

Notwithstanding the Examiner's assertions as to what each of SLAMA and SCHRAGA discloses or suggests, Applicant submits that no proper combination of these documents discloses or suggests: <u>inter alia</u>, a main spring disposed between the front and rear ends of the holding member and a second stop surface axially retained to a front

portion of the body, as recited in independent claim 43; and <u>inter alia</u>, a back cap configured to move the holding member to a retracted position, a second spring disposed between the rear end of the holding member and a surface of the back cap, and a second stop surface axially retained to a front portion of the body, as recited in independent claim 44.

Applicant acknowledges that SLAMA discloses a lancet device which utilizes, among other things, a body 2, a front cover 10, and a holding member 3. Nor does Applicant dispute that the front end of the holding member 3 has forms a first stop surface which moves and engages with a second stop surface arranged on a rear end of the front cover 10. Indeed, Fig. 4 of SLAMA clearly shows such contact. However, it is clear that the second stop surface (i.e., the one arranged on the rear end of the front cover 10) is not axially retained to a front portion of the body 2. To the contrary, this surface is arranged on a rear end of the front cover 10 and not the body 2. Nor is this surface properly characterized as axially retained. As the Examiner will note from Fig. 3, rotation of the front cover 10 will cause this surface to move axially. A surface which can move axially and which is arranged on a front cover 10 simply cannot be characterized as a surface that is axially retained to a front portion of the body.

It is also clear that SLAMA fails to disclose, or even suggest, a main spring disposed between the front and rear ends of the holding member. Indeed, the Examiner has acknowledged as much in the instant Office Action.

It is further also clear that SLAMA fails to disclose, or even suggest, a back cap configured to move the holding member to a retracted position and/or a second spring

Indeed, the Examiner has failed to identify any of these features in SLAMA. Nor can the Examiner do so from a fair review of the figures of SLAMA. As the Examiner will note from Figs. 1-5, the body 2 has a closed rear end and merely utilizes a single spring 4.

With regard to SCHRAGA, Applicant acknowledges that SCHRAGA discloses a lancet device (see e.g., Fig. 16) which utilizes, among other things, a body, a front cover, a holding member, two springs and a back cap. However, it is clear that the second stop surface 28, while being non-movably coupled to the body and extending inwardly therefrom (see Fig. 2), is not arranged between the first stop surface and the skin engaging end.

It is also clear that SCHRAGA fails to disclose, or even suggest, the combination of a first stop surface coupled to or arranged on a front portion of the holding member and a second stop surface axially retained to a front portion of the body. To the contrary, Fig. 2 shows the second stop surface 28 arranged at a rear portion of the body and not on a front portion of the body. Moreover, the first stop surface, while clearly coupled to the holding member 32, is not coupled to or arranged on a front portion of the holding member 32. To the contrary, Fig. 2 shows a first stop surface coupled to member 33 which is arranged on the rear portion of the holding member 32.

Thus, Applicant submits that the above-noted documents fail to disclose or suggest the features recited in at least independent claims 43 and 44. Because no proper combination of the above-noted documents discloses or suggests at least the above-noted features of the instant invention, Applicant submits that no proper modification of these documents can render unpatentable the combination of features recited in at least

independent claims 43 and 44.

Furthermore, Applicant submits that there is no motivation or rationale disclosed or suggested in the art to modify any of the applied documents in the manner asserted by the Examiner. Nor does the Examiner's opinion provide a proper basis for these features or for the motivation to modify these documents, in the manner suggested by the Examiner. Therefore, Applicant submits that the invention as recited in at least independent claims 43 and 44 is not rendered obvious by any reasonable inspection of these documents.

Applicant requests that the Examiner reconsider and withdraw the rejection of the above-noted claims under 35 U.S.C. § 103(a).

# **CONCLUSION**

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipates or renders obvious the Applicant's invention, as recited in each of the pending claims. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

The Commissioner is hereby authorized to refund excess payments and charge any additional fee necessary to have this paper entered to Deposit Account No. 19-0089.

Should the Examiner have any further comments or questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted, S. SCHRAGA

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